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Weitzner

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[54] **DEVICE FOR FEMALE PATIENTS TO PREVENT INVOLUNTARY LOSS OF URINE**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 441,089, May 15, 1995, abandoned.

[51] **Int. Cl.⁶** **A61F 2/00**

[52] **U.S. Cl.** **600/29; 600/30; 600/31**

[58] **Field of Search** **600/29, 31**

[56] **References Cited**

U.S. PATENT DOCUMENTS

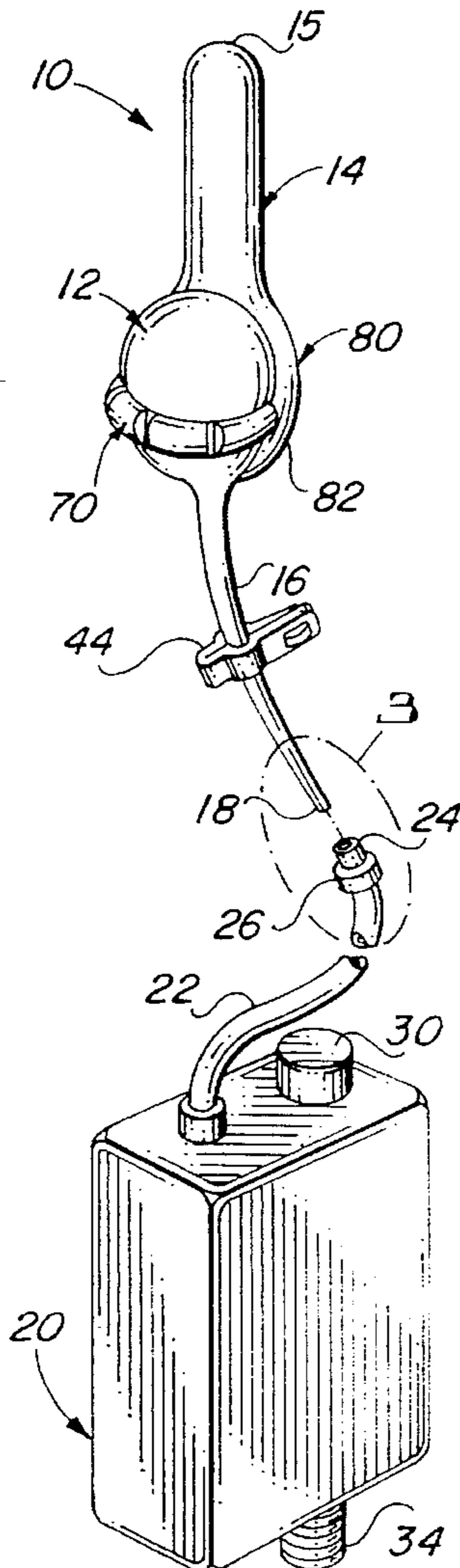
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[57] **ABSTRACT**

An intra-vaginal device includes an anterior inflatable body having a hose extending therefrom and a pressure application zone structured and disposed to direct pressure against the urethra and urethra vesicle junction when inflated, to thereby prevent loss of urine. A posterior portion extends from the inflatable anterior body, terminating at a distal end, and is structured and configured to promote insertion and passage of the device within the vagina. A source of pressurized air is releasably attachable to a distal end of the hose to facilitate inflation of the anterior body.

7 Claims, 2 Drawing Sheets



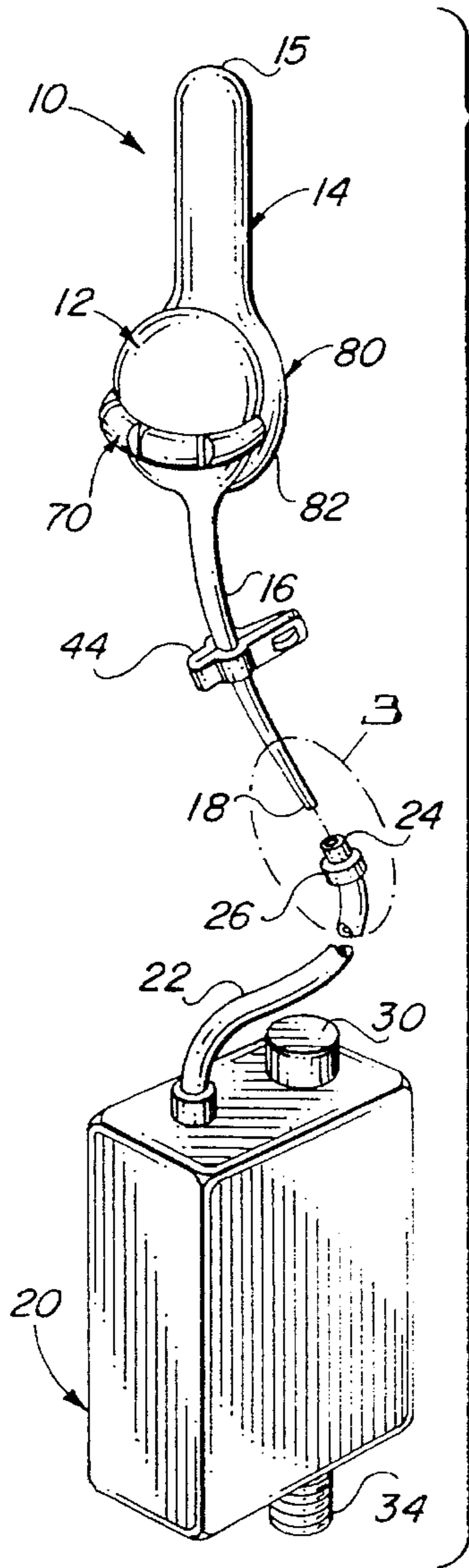


FIG. 1

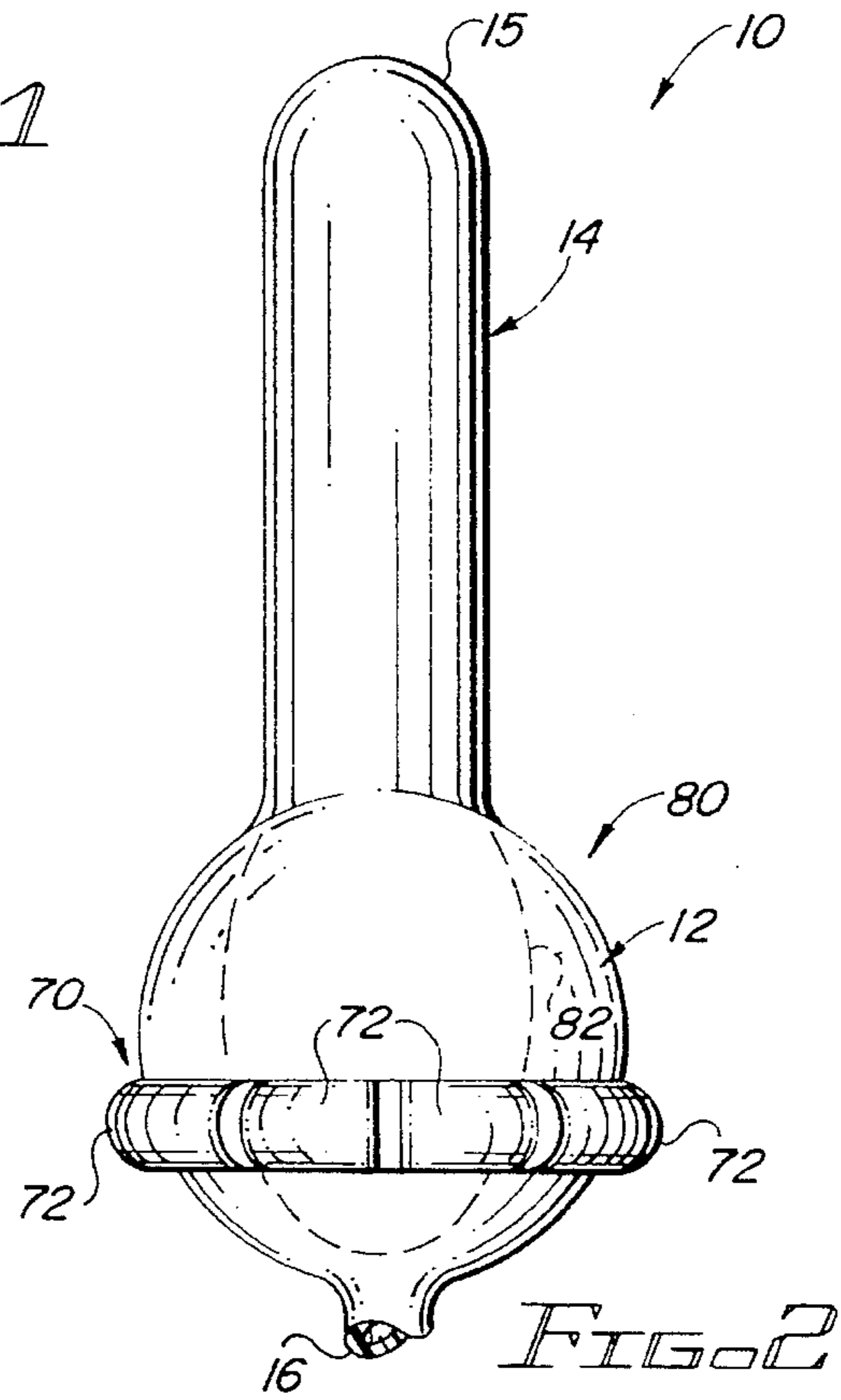


FIG. 2

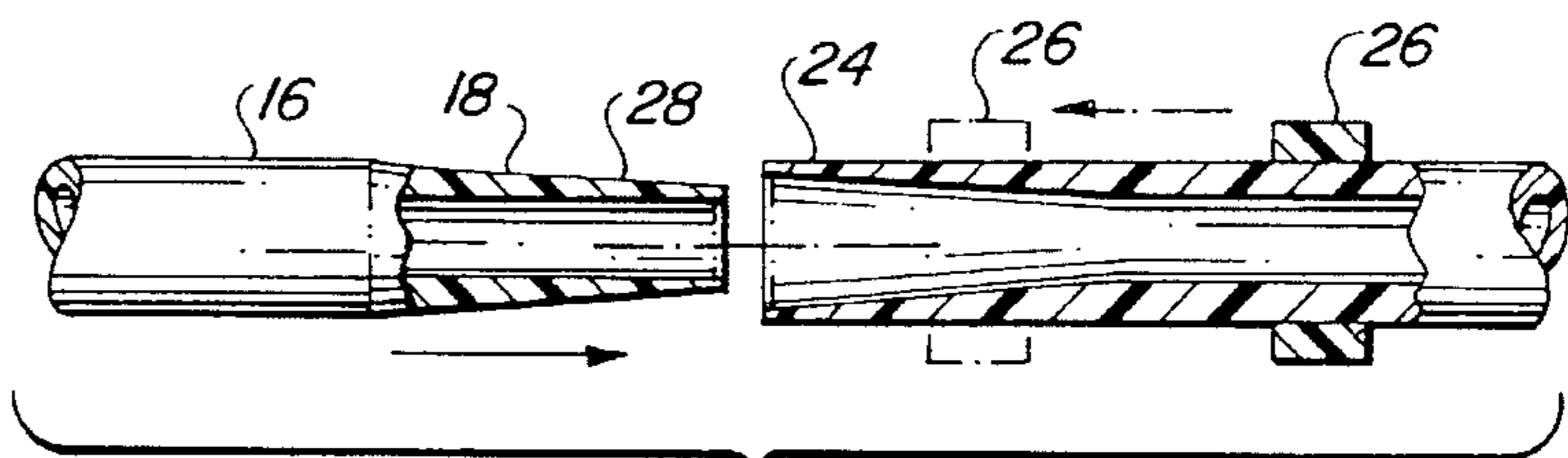


FIG. 3

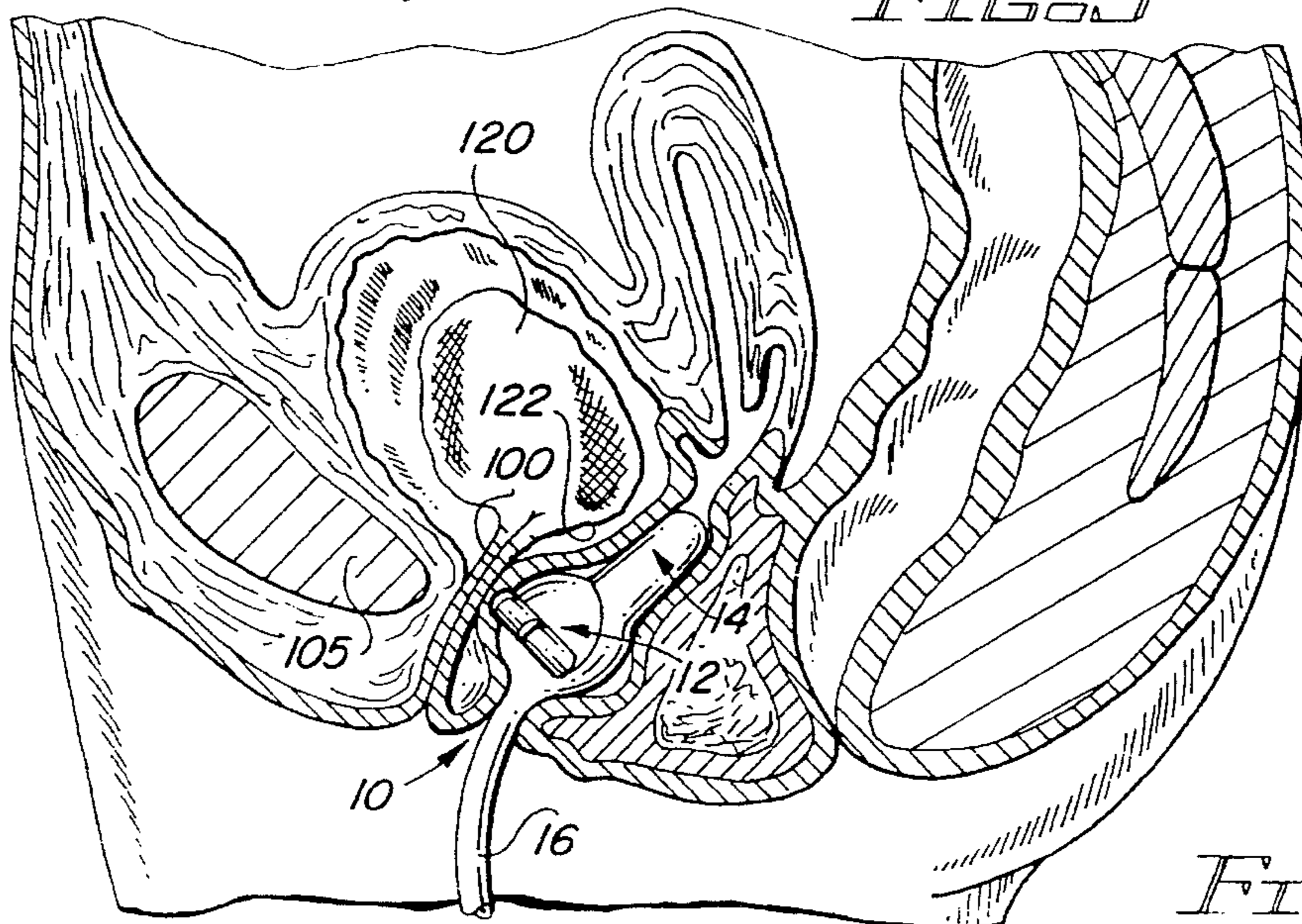
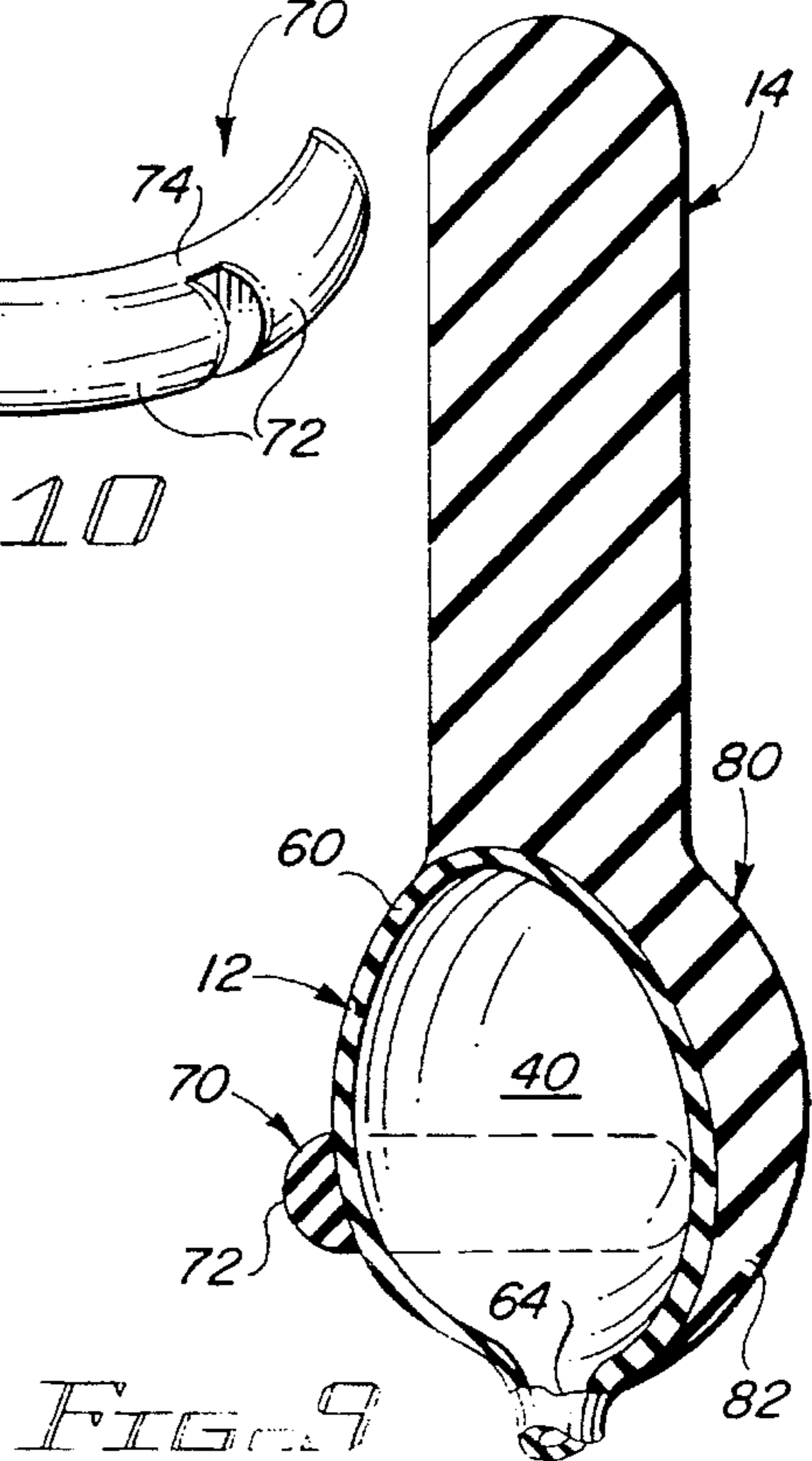
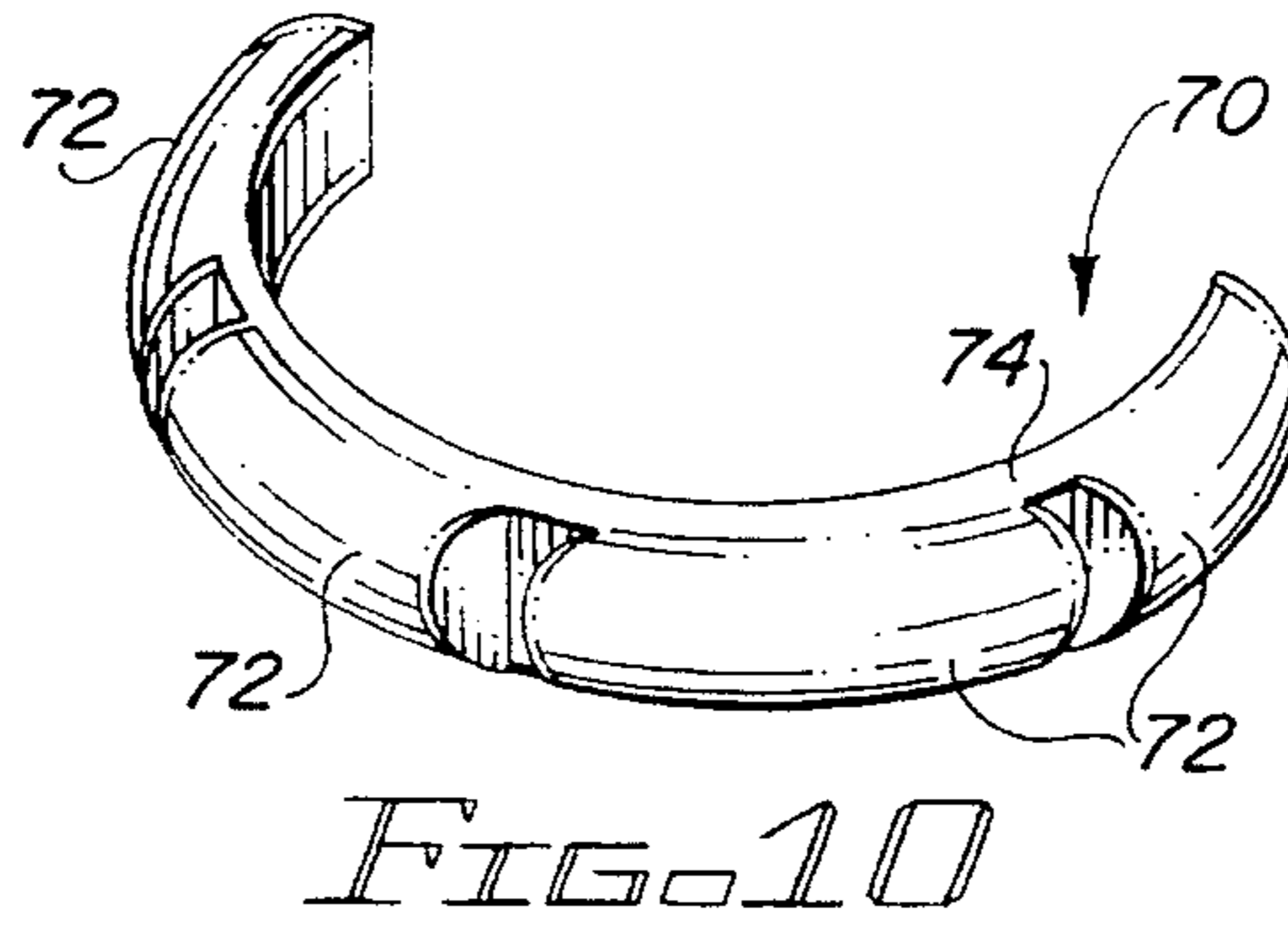
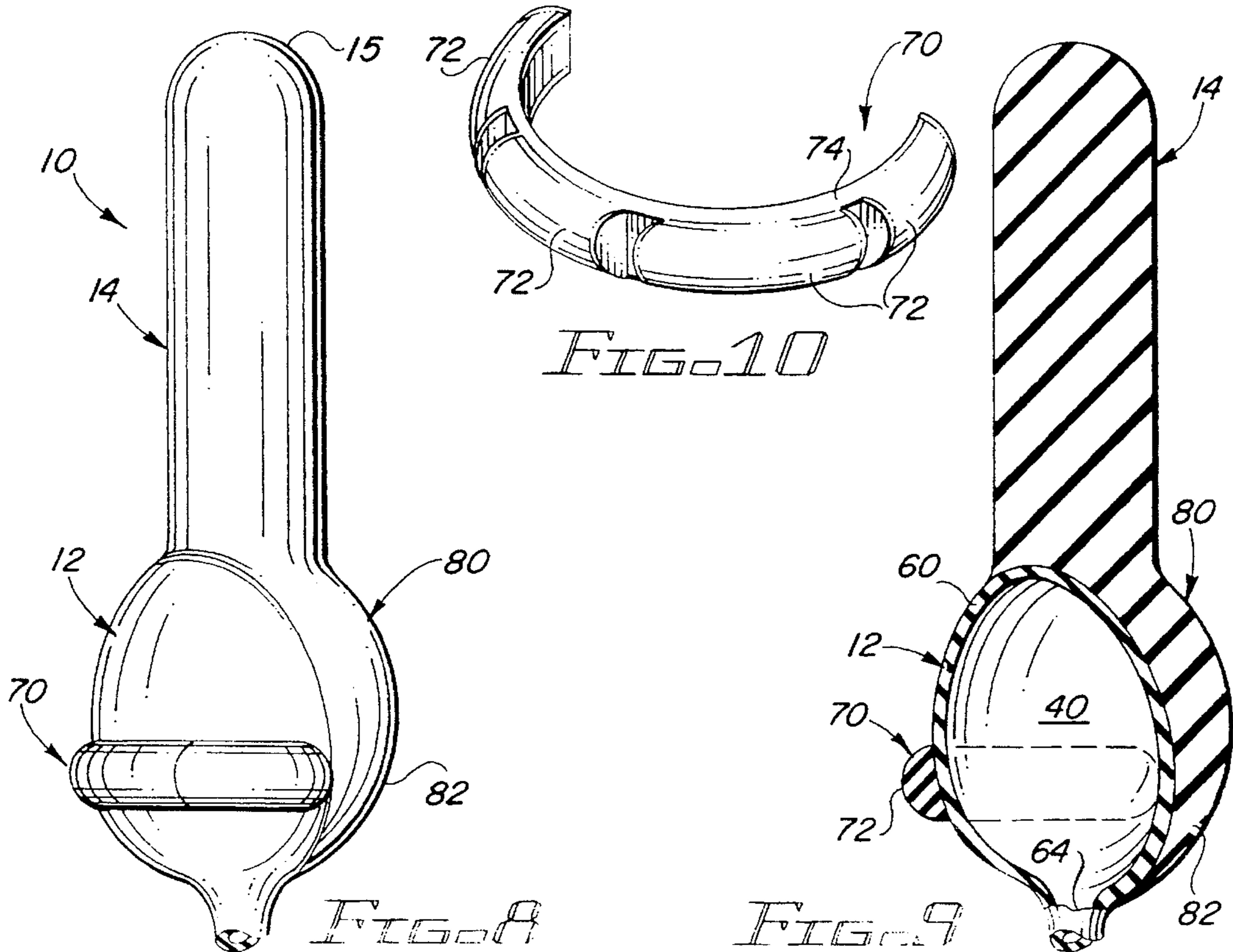
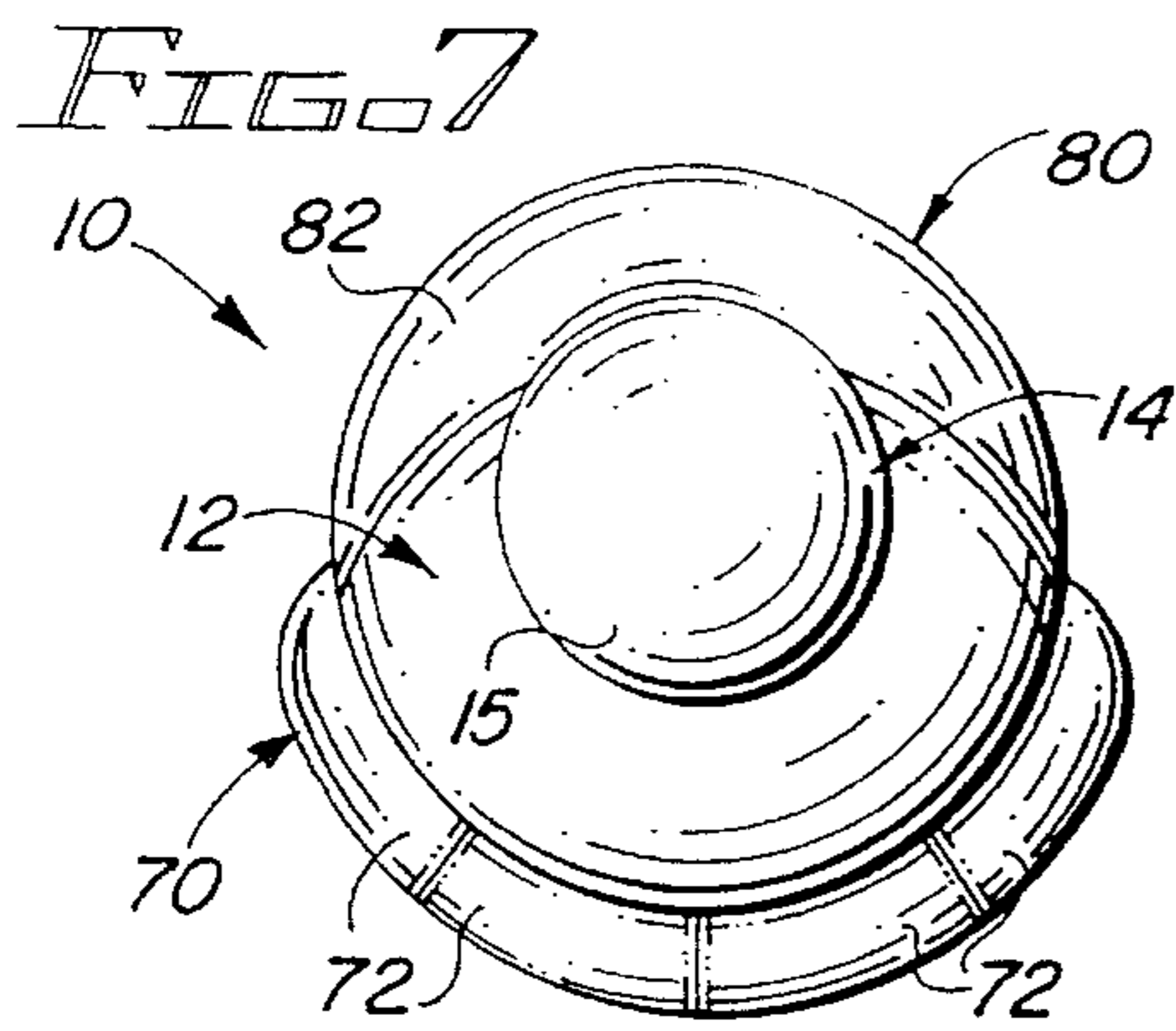
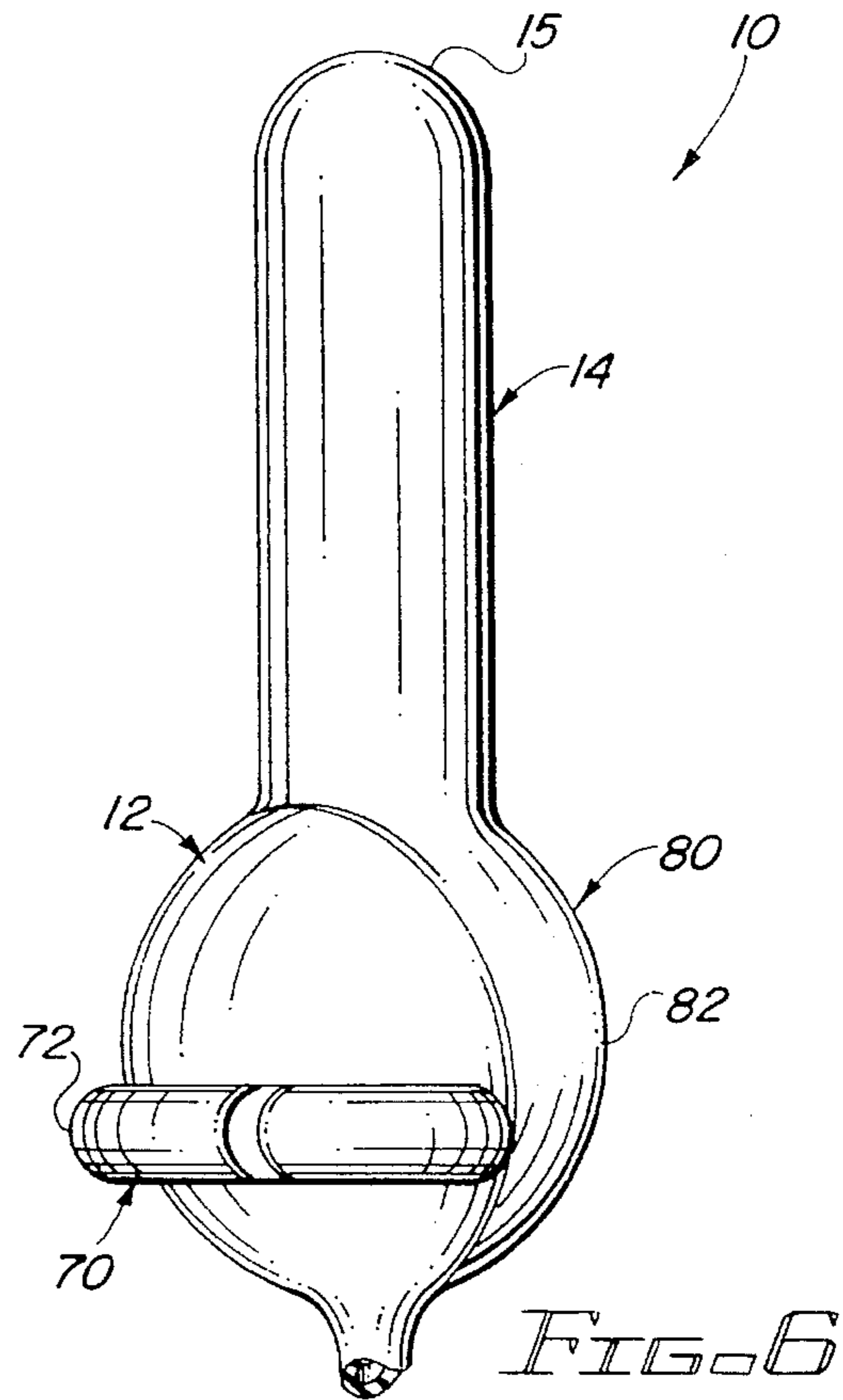
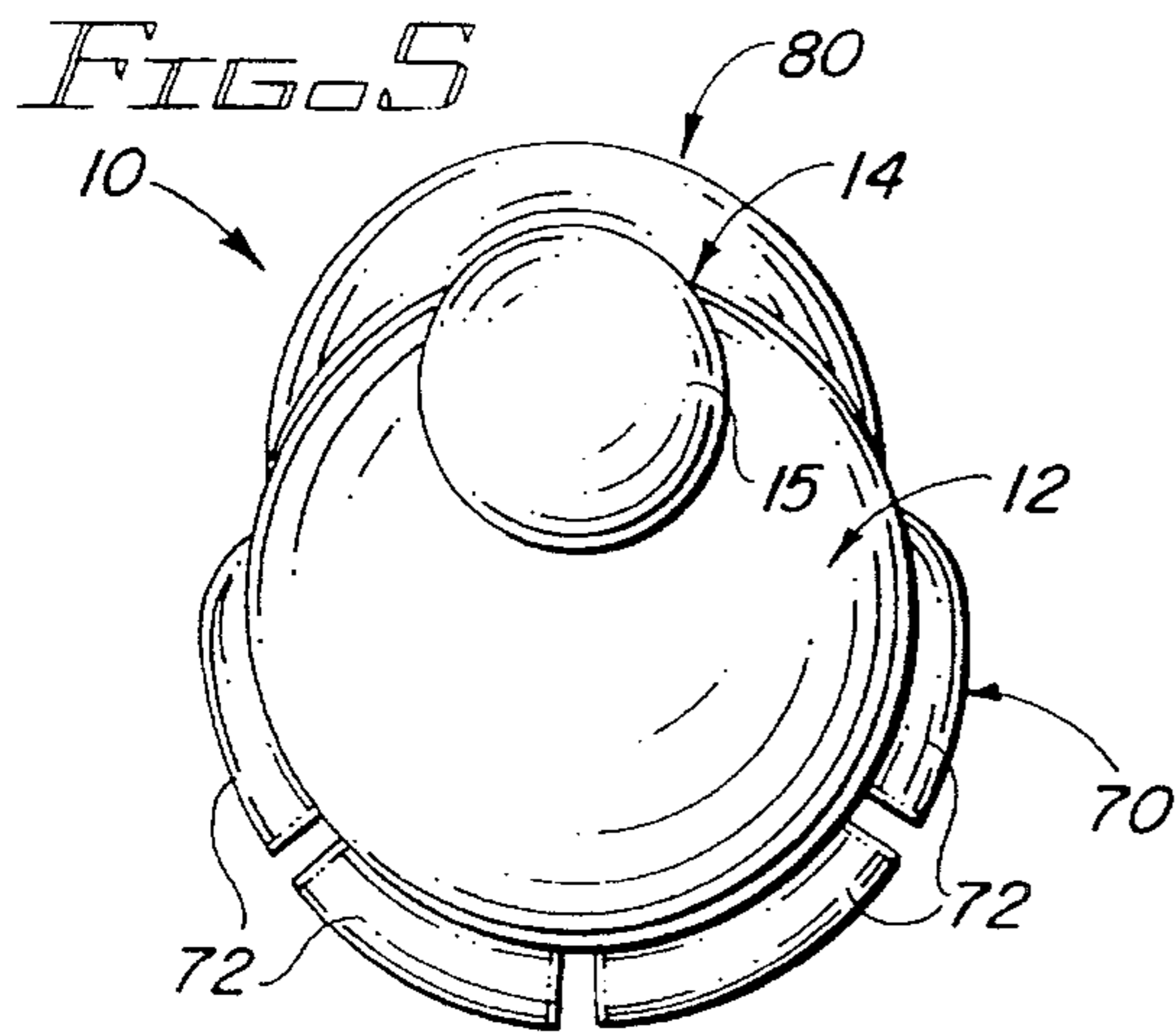


FIG. 4



DEVICE FOR FEMALE PATIENTS TO PREVENT INVOLUNTARY LOSS OF URINE

This application is a continuation-in-part application of application Ser. No. 08/441,089 filed on May 15, 1995 now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is directed to a vaginal prosthesis, and more specifically to an inflatable device adapted to be inserted within the vagina to prevent involuntary loss of urine.

2. Description of the Related Art

Urinary stress incontinence is defined as the involuntary, sudden loss of small amounts of urine under sudden increases in intra-abdominal pressure as results from coughing, sneezing, squatting, etc. In genuine or pure stress incontinence, there should be no detrusor muscle activity present, as even slight contractions of the bladder may contribute to loss of urine.

There have been many different operations, drugs, medications, active and passive muscle stimulations, and internal vaginal devices devised and used either singularly or in combination to improve or cure this condition. The problem with each of these modalities is that there is a considerable difference in reported outcomes by different investigators using them. Therefore, there is no agreement amongst authorities as to which one of the many choices is superior. However, most medical experts agree that given a choice between non-surgical and surgical methods, the non-surgical approach should be tried first and, if unsuccessful, then surgery should be considered.

SUMMARY OF THE INVENTION

The present invention is a vaginal prosthesis for the correction of stress incontinence which achieves the same beneficial results as surgery. Specifically, the device of the present invention achieves: 1) elevation of the urethra vesicle junction; 2) increased resting intra-urethral pressure; 3) posterior rotation of the bladder so that the floor of the bladder and not the urethra vesicle junction becomes the most dependent portion of the bladder mechanism in the upright position.

In accordance with the present invention, there is a device containing an anterior inflatable body operable under measured pressure to perform the above functions without causing pressure necrosis of the vaginal mucosa. The anterior body, when inflated to 30 mm of Hg or less, applies pressure to the urethra and the urethra vesicle junction, resulting in elevation and an increase of intra-urethral resting pressure while preventing pressure wounds from forming in the vagina.

A posterior portion extends from the anterior inflatable body and is sized and configured to facilitate insertion and passage of the device within the vagina. With the device properly inserted and inflated, the reduced diameter of the posterior portion relative to the inflated portion allows the floor of the bladder to descend and receive most of the force of intra-abdominal pressure, from coughing, sneezing, or squatting.

Accordingly, with the foregoing summary in mind, it is an object of the present invention to provide a device for controlling involuntary loss of urine and which is specifi-

cally structured to achieve: elevation of the urethra vesicle junction; an increase in resting intra-urethral pressure; and posterior rotation of the bladder.

It is a further object of the present invention to provide an intra-vaginal device structured to be inflated once inserted within the vagina and including a pressure application zone specifically structured and disposed to apply pressure against the urethra and the urethra vesicle junction.

It is still a further object of the present invention to provide an intra-vaginal device for controlling involuntary loss of urine which is easily insertable, removable and checkable by the patient for proper positioning in the vagina.

It is still a further object of the present invention to provide an intra-vaginal device which can be used alone for the correction of stress incontinence or as a supplement with other modalities.

It is yet a further object of the present invention to provide a vaginal prosthesis for correction of stress incontinence which is safe and yet which provides the same beneficial results as surgery at a significantly lower cost and health risk to the patient.

These and other objects and advantages of the present invention will be more readily apparent in the description which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature of the present invention, reference should be had to the following detailed description taken in connection with the accompanying drawings in which:

FIG. 1 is a perspective view of the intra-vaginal device of the present invention shown with a handheld pressurized air source adapted to be interconnected to the device for inflation after the device is inserted into the vagina;

FIG. 2 is a front elevation view of the intra-vaginal device;

FIG. 3 is an isolated plan view in partial section illustrating attachment of the hose of the intra-vaginal device to a hose extending from the handheld pressurized air source;

FIG. 4 is a sectional anatomic view showing the device properly positioned within the vagina applying pressure to the urethra vesicle junction;

FIG. 5 is a top plan view of the intra-vaginal device, shown inflated;

FIG. 6 is a side elevation of the intra-vaginal device in the inflated state;

FIG. 7 is a top plan view of the intra-vaginal device, shown in a deflated state;

FIG. 8 is a side elevation of the intra-vaginal device in the deflated state;

FIG. 9 is a side sectional view of the device in the deflated state; and

FIG. 10 is an isolated perspective view of a collar having spaced bulge segments which is fixedly attached to the anterior inflatable body to create a pressure application zone.

Like reference numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the several views of the drawings, there is illustrated the various embodiments of the device, generally

indicated as **10**, for preventing involuntary loss of urine in women.

Referring initially to FIGS. **1**, **2**, **6** and **8**, a preferred embodiment of the device **10** is shown and includes an anterior inflatable body **12**, a posterior aft portion **14** terminating at a blunt distal end **15**, and a hose extension **16** extending from the anterior body portion **12**. In use, the posterior portion **14** and anterior body **12** are inserted within the vagina with the anterior body in a collapsed, deflated, relaxed state. Once properly inserted and positioned, with the hose **16** extending exteriorly of the vagina, a pressurized air source is connected to the distal end **18** of the hose **16** to inflate the anterior body **12** to a predetermined pressure, preferably not greater than 30 mm of Hg.

In a preferred embodiment, a handheld device **20** is provided, having a pressurized canister or other air pressure cylinder or chamber contained therein. The handheld device **20** includes an air supply hose **22** extending therefrom and terminating at a distal end **24**. Referring to FIG. **3**, the male distal end **24** of the hose **22** is attachable to a female end **28** on the distal end of the hose extension **16** of the device **10**. A sliding collar **26**, or like attachment means, facilitates removable attachment of the male **24** and female **28** ends by applying pressure about male end **24** to hold the female end **28** therein. Once attached, a button **30** or other actuation mechanism on the handheld device **20** is operated to release pressurized air flow through the air supply hose **22** and through the attached hose extension **16** into an interior air chamber of the anterior body **12**, resulting in inflation thereof to the predetermined pressure, and thus activating the device. A fitting **34** on the handheld device **20** may be provided to facilitate attachment to a compressor or larger air supply for refilling of the pressurized air supply within the chamber of the handheld device **20**.

Once the anterior body **12** is inflated to the desired pressure (30 mm of Hg or less), the hose **16** needs to be closed off, prior to disconnection of the air supply hose **22**, to prevent deflation of the anterior body **12**. This may be accomplished through the use of a clip **44** which releasably clips along the length of the hose extension **16**, pinching off the hose and preventing air from escaping from within the interior air chamber. Alternatively, other means may be provided such as a valve fitted in-line along the hose extension **16** and being operable by the patient to close off the air chamber. When it is necessary to remove the device, the clip **44** or other closure means can be removed or opened by the patient, thereby releasing the charge of pressurized air from within the interior air chamber of the anterior body **12**, resulting in deflation and at least partial collapse of the anterior body **12**. In this manner, the reduced size of the device enables easy removal from within the vagina. A Y-shaped portal with valve means therein is another acceptable closure means.

Referring to FIG. **9**, the device **10** is illustrated in cross section (in a deflated state), wherein the anterior body **12** is preferably 3 cm in length and includes an outer wall structure **60**, at least partially formed of an impermeable, elastomeric membrane in surrounding relation to the interior air chamber **40** of the anterior body **12**. An air passageway **64** is formed at a front end of the anterior body, being integral with the hose extension **16** to define an air passage channel from the distal end of the hose extension **16** to the interior air chamber.

The anterior body **12** is further provided with a pressure application zone **70** specifically structured and disposed to exert a predetermined amount of pressure, preferably 30

mm, against an abutting surface when the anterior body is inflated to the operative state. In FIGS. **2**, **5** and **6**, the device is shown in the inflated operative state, wherein the interior air chamber is filled with the predetermined charge of pressurized air causing the pressure application zone to bulge outwardly. Accordingly, with the device inserted and properly positioned within the vagina, as seen in FIG. **4**, the pressure application zone **70** exerts pressure against the urethra vesicle junction **100** in the direction of the symphysis pubis **105**. This serves to elevate the urethra vesicle junction **100**, while increasing resting intra-urethral pressure to close off the urethra.

Referring to FIGS. **6**, **8** and **9**, the posterior portion **14** is integrally attached to the anterior body **12** and extends therefrom. The posterior portion **14** is longer than the anterior body **12**, preferably 6 cm in length, and terminates at a distal end **15**. The distal end **15** is slightly rounded to eliminate sharp edges. The rounded distal end **15** and elongate configuration of the posterior portion **14** serve to promote travel within the vagina while discouraging damage to the vaginal wall. With the device **10** properly inserted and inflated to the operative state, as seen in FIG. **4**, the reduced diameter of the posterior portion **14** relative to the anterior body **12** allows the floor **122** of the bladder **120** to become more dependent and receive most of the increase of intra-abdominal pressure. This also causes posterior rotation of the urethra and bladder.

The anterior body is seated and attached within a partial shell formed of a semi-rigid material and which is integral with the posterior portion **14**. The partial shell **80** includes a spoon-shaped portion **82** sized and configured for attached receipt of the anterior body therein so that the spoon-shaped portion is disposed on an exterior of the outer wall structure **60**, opposite of the pressure application zone **70**. The spoon-shaped portion **82** includes a rounded exterior configuration, integrally formed with said posterior portion **14** to provide a smooth, uninterrupted overall configuration which is compatible with the anatomy of the vagina, thereby promoting insertion and removal of the device **10**. The partial shell **80**, not being expandable, further serves to direct air pressure upwards within the interior air chamber **40** towards the pressure application zone **70** to promote expansion thereof. Because of the semi-rigid, non-expanding nature of the shell **80**, the portion of the outer wall structure **60** of the anterior body **12** which engages the spoon-shaped portion **82** is prevented from expanding outwardly. This serves to promote more definite outward expansion of the pressure application zone **70**, as this area of the outer wall structure **60** has less resistance to expansion than the area within the spoon-shaped portion **82**.

The spoon-shaped portion **82** is best illustrated in FIGS. **2**, **6** and **8** and is specifically shaped and configured to promote insertion and removal of the device for proper positioning within the vagina. It also ensures anterior bulging of the inflatable portion upwards towards the urethra rather than downwards towards the rectum.

Referring to FIGS. **2** and **5-10**, and in particular FIG. **10**, a preferred embodiment of the pressure application zone **70** is shown to include a collar element **74**. The collar element **74** is preferably formed of an elastomeric material and is fixedly attached to the exterior of the outer wall structure **60** of the anterior body **12** using a suitable bonding compound. The collar element is provided with a plurality of spaced bulge segments **72** which are specifically structured and configured to exert concentrated pressure at the urethra vesicle junction. The spacing of the segments **72** allows the collar **74** to expand as the anterior body **12** is inflated to the

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operative state. The segments 72 are spaced far enough apart so that they will not pinch the vaginal wall when the device is deflated.

The device should be inserted vaginally with the aid of a lubricating jelly such as KY. Another alternative would be an estrogen cream or a mild antiseptic vaginal jelly. A water soluble base is preferred.

While the instant invention has been shown and described in what is considered to be preferred and practical embodiments, it is recognized that departures may be made within the spirit and scope of the invention as set forth in the claims and within the doctrine of equivalents.

Now that the invention has been described,

What is claimed is:

1. An intra-vaginal device for controlling involuntary loss of urine comprising:

an anterior inflatable body including an outer wall structure and a hollow interior air chamber structured to receive a charge of pressurized air to expand said anterior inflatable body from a relaxed, at least partially collapsed state to an operable inflated state to define an enlarged diameter thereof, said anterior inflatable body including an air passage opening disposed in communication with said air chamber,

pressure application means on said anterior inflatable body for applying concentrated pressure to an abutting surface when said anterior inflatable body is inflated to said operable state,

said pressure application means including at least one bulge segment protruding from said outer wall structure,

a posterior portion integral with and extending from said anterior inflatable body and having an elongate configuration with a reduced diameter relative to said enlarged diameter of said anterior inflatable body and terminating at a rounded distal end to promote insertion and passage of said posterior portion and said anterior inflatable body within the vagina,

an air passage conduit extending from said air passage opening and terminating at a free distal end, said air passage conduit being structured and disposed to facilitate air flow therethrough into and out from said air chamber, and

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closure means for selectively and controllably blocking air flow between said air chamber and said distal end of said air passage conduit to thereby capture said charge of pressurized air within said air chamber, maintaining said anterior inflatable body in said operable inflated state.

2. A device as recited in claim 1 wherein said posterior portion includes an integral partial shell structure formed of a semi-rigid material and including a spoon-shaped portion structured and disposed to receive the anterior inflatable body therein, said spoon-shaped portion having a rounded exterior configuration integrally formed with said elongate configuration of said posterior portion to promote insertion and removal of the device within the vagina and to promote expansion of said anterior inflatable body at said pressure application means.

3. A device as recited in claim 2 wherein said partial shell structure is disposed on an exterior of said outer wall structure of said anterior inflatable body, opposite of said pressure application means.

4. A device as recited in claim 1 wherein said outer wall structure is formed at least partially of a resilient impermeable membrane.

5. A device as recited in claim 4 wherein said closure means includes a clip structured for removable attachment to said air passage conduit, said clip being specifically structured to block air flow through said air passage conduit when attached thereto, thereby preventing air from escaping from within said air chamber.

6. A device as recited in claim 5 wherein said posterior portion includes an integral partial shell structure formed of a rigid material and including a spoon-shaped portion having a rounded exterior configuration integrally formed with said elongate configuration of said posterior portion to facilitate insertion and removal of the device within the vagina.

7. A device as recited in claim 6 wherein said spoon-shaped portion is sized and configured for attached receipt of said anterior inflatable body therein so that said spoon-shaped portion is disposed on an exterior of said outer wall structure of said anterior inflatable body, opposite of said pressure application means, to promote expansion of said anterior inflatable body at said pressure application means.

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